value of such observational datasets, relative to the construction or use of RCT study designs. **METHODS:** A systematic review of a health economics literature database (HEED) was conducted to explore the use of observational and RCT data in applied pharmacoeconomic evaluations in the UK (1990–1999). A comparative analysis of longitudinal datasets (containing resource use and outcomes data) developed in the UK (e.g. DIN-LINK, GPRD) was undertaken with an assessment of the potential analytical approaches (multivariate techniques, cross-design synthesis) and methodological and practical considerations. **RESULTS:** A total of 71 studies were identified, 59 CEAs only, 6 CUAs only and 6 where both CEAs and CUAs were conducted. The table presents the type of data used in these studies for the three core data items of a pharmacoeconomic evaluation. RCT data represented the majority source for all three items, in particular for clinical event and disease outcome data. Observational data sources were more frequently used to provide resource use consequence data. None of the reviewed studies made use of any existing prospective or retrospective database. **CONCLUSIONS:** Regardless of the system of health care, there is an obvious and universal need for reliable data on the effectiveness and costs of clinical interventions. Observational datasets have implications for outcomes research conducted in pharmaceutical companies. There is little literature on the use of observational data in economic evaluation, and more debate on this subject is needed. As we gain a better understanding of the tradeoffs between internal and external validity, it is predicted that more pharmacoeconomic analyses will increasingly be based on observational data or a combination of observational and RCT data.

	Data source	
	Observational	RCT
Resource use consequences	21	27
Clinical events	19	37
Disease outcomes	19	33
All 3 sets of core data	9	14

	Data source	
Core data for economic evaluations	Observational & RCT	Other
Resource use consequences	3	20
Clinical events	6	9
Disease outcomes	6	13
All 3 sets of core data	1	6

PMT2

RELIABILITY OF PRESCRIPTION CLAIMS DATA FOR HEALTH CARE RESEARCH

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OBJECTIVES: To evaluate the accuracy of claims versus original prescriptions by calculating the match rate for 7 fields: drug, strength, dosage form, quantity, day's supply, daily dose, and date dispensed. Claims accuracy was also analyzed by therapeutic class for antibiotics, oral hypoglycemics, H_2 antagonists, antipsychotics, and antidepressants. **METHODS:** Purdue's Pharmaceutical Economics Research Center (PERC) systematically recruited 10 pharmacies from a random list generated by pharmacy benefits manager PCS Health Systems, Inc. (PCS). PCS randomly extracted 500 claims submitted by each pharmacy between 07/01/96 and 06/30/97. Pharmacies obscured patient information and photocopied the original prescriptions. Trained assistants abstracted 5 fields and calculated day's supply and daily dose from the directions for use. **RESULTS:** Six of 10 pharmacies provided 2,938 photocopies, split approximately evenly among therapeutic classes. Overall match rates were: drug (99.9%), strength (97.0%), dosage form (95.5%), quantity (94.1%), day's supply (85.2%), daily dose (83.2%), and date dispensed (65.1%). Applicable mean percentage differences were: strength (1.32%), daily dose (2.53%), day's supply (2.73%), and quantity (6.03%). The mean difference for date dispensed was 19.3 days. Match rates were comparable for antidepressants, antipsychotics, and H_2 antagonists. Antibiotic and oral hypoglycemic rates were more variable. **CONCLUSIONS:** Claims reliability was excellent for drug, strength, dosage form, and quantity and good for day's supply and daily dose. Antidepressant, antipsychotic, and H_2 antagonist classes had comparable reliability. The reliability of date dispensed appeared questionable, but the dates recorded by hand on prescriptions were later than those automatically submitted for claims, suggesting that claims data may be more accurate than the original prescriptions. This study found prescription claims to be a reliable data source for health care research.

PMT3

PREDICTING DRUG SPENDING: UPDATE AND EVALUATION OF A REVISED CHRONIC DISEASE SCORE

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When conducting economic analyses using administrative claims, it is important to account for the impact of comorbidities on healthcare costs. The Chronic Disease Score (CDS) is a useful risk-adjustment tool for use in pharmacy claims-based research, however the published version does not include important new drugs and the weights were developed from smaller, geographically restricted databases. **OBJECTIVES:** The purpose of this study is to: (1) update the number and types of drugs included in the CDS (2) develop new weights based on a large, multi-region pharmacy claims database, and (3) evaluate the revised CDS in explaining variations in and predicting drug expenditures. **METHODS:** Analyses

were conducted using a leading PBM's research sample that contains prescription claims from 3.9 million beneficiaries. Continuously eligibles for 1997 and 1998 were included. A mapping algorithm was developed to link each of 27 diseases with their corresponding medication classes using Standard Therapeutic Class and/or Hierarchical Ingredient Code List codes. A weight system was developed based on relative costs derived using multivariate regression. The second-year drug costs were predicted based on the first-year demographic and CDS scores. To assess the accuracy of the prediction models, a random split-sample method was applied. **RESULTS:** The revised CDS was moderately correlated with age ($r = 0.42$) and had a high year to year correlation of 0.83. It performed significantly better in explaining variations in and predicting costs than the demographic model. Adjusted R-Square for fitting was fourfold higher: 0.65 vs. 0.15 for log-transformed costs (0.32 vs. 0.06 for actual dollars). **CONCLUSION:** The revised CDS is better than demographics in explaining the variations in prescription drug costs and predicting the future costs, however further validation work is required. We plan to compare the revised CDS with the old version to determine the incremental improvement in predicting both drug and medical cost.

PMT4

METHODOLOGICAL ISSUES IN ESTIMATING DISEASE PROGRESSION: IS MARKOV MODEL THE BEST METHOD?

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Markov model is a technique for analyzing events that repeat or extend over a long period of time. It has been widely applied to examine the progressions of disease with well-defined "markers" such as HIV. Most studies using Markov models suffer from a major limitation of the "no-memory" assumption. **OBJECTIVE:** This study uses HIV cases as an example to demonstrate an alternative disease progression model: a history- and duration-dependent transition probability model. **METHODS:** This general transition probability model captures patient's history of disease states (history-dependency) by categorizing HIV patients into three types, stable, progress, and recess, based on whether the patients had the same disease state, a less severe state, or a more severe state at the previous cycle. For patients with a history of "stable" disease states, duration in that state was also included in the model (duration-dependency). Data from the Multicenter AIDS Cohort Study (MACS) was used to model the disease progression of HIV patients in four US cities since 1984. Five disease states were constructed using ranges of the CD4/CD8 ratio as the "marker". They are: >0.63, 0.42–0.63, 0.31–0.42, <0.31, and death. The cycle length is 6 months. **RESULTS:** Compared with estimates obtained from either Markov chain or Markov process models, this general transition probability model yields better prediction of life expectancies and allows more flexibility in modeling the disease progression. **CONCLUSIONS:** By refining the disease progression process, our transition probability model provides a better way to evaluate the effectiveness as well as cost-effectiveness of treatment alternatives and/or impacts from alternative health policies.

PMT5

DEVELOPMENT OF MULTI-LANGUAGE PATIENT OUTCOME ASSESSMENTS

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OBJECTIVES: Inclusion of patient outcome assessments in international clinical trials necessitates that cross-culturally valid instrument data be pooled across countries. Our primary objective is to discuss the development of patient outcome assessments for use in international trials of patients with upper gastrointestinal disorders. **METHODS:** We reviewed the literature and conducted interviews with subjects and clinical experts prior to developing symptom and quality of life (QOL) instruments for patients with upper GI disorders. The instruments were reviewed by clinical experts and cognitive debriefing of subjects was performed. Following these procedures, forward and backward translation of the instruments into twenty languages was performed. **RESULTS:** A total of approximately 120 subjects with gastroesophageal reflux disease, dyspepsia, or gastroparesis and 12 clinical experts from six countries were interviewed to determine symptoms and QOL issues they deemed important. The resulting instruments are the Patient Assessment of Upper GastroIntestinal Disorders-Symptom Severity Index (PAGI-SYM) and Quality of Life Index (PAGI-QOL). The PAGI-SYM contains 37 items and six modules representing heartburn, reflux/regurgitation, nausea/vomiting, abdominal pain/discomfort, bloating/early satiety/fullness and other symptoms. The PAGI-QOL has 49 items divided into two sections, QOL and a general section. The QOL section is comprised of seven modules: daily activities, concentration/sleep, social activities, clothing, diet, relationships, and psychological state/emotions. The general section contains six items measuring severity of GI problems, satisfaction, and relief. **CONCLUSION:** Outcome measures for international trials should undergo comprehensive development and rigorous linguistic validation processes. Initial psychometric testing is currently underway to ensure the instruments will behave appropriately across countries.